ElliQ Study Protocol:

Effect of a Proactive Social Robot for Older Adults in Reducing Loneliness and Social Isolation

April 16, 2019

STUDY TEAM

Institutions

<u>Study Sponsor</u>: Intuition Robotics

<u>Study Funder</u>: Centre for Aging and Brain Health Innovation ("CABHI")

<u>Health Information Custodian</u>: Baycrest; Jewish Senior Living Group of San Francisco (JSLG)

Evaluation Team

<u>Principal Investigator</u>: Allison Sekuler, PhD – Vice-President, Research; Managing Director, Rotman Research Institute

<u>Co-Investigator</u>: Rosanne Aleong, PhD – Director, Research, Innovation, and Translation, Rotman Research Institute, Baycrest

<u>Co-Investigator</u>: Jed Meltzer, PhD – Neurorehabilitation Scientist, Rotman Research Institute, Baycrest

<u>Co-Investigator</u>: Christine S. Ritchie, MD, MSPH, Senior Scientist at SFCJL and Professor of Medicine

<u>Co-Investigator</u>: Michael Steinman, MD, Visiting Research Scientist at SFCJL and Professor of Medicine

<u>Co-Investigator</u>: Michael Skaff, Chief Operating Officer, SFCJL

PROJECT SUMMARY

Background Research

The proportion of the Canadian population aged 65 years and older has been increasing over the past 40 years.[1] Between 1971 and 2010, the proportion of older adults in the population grew from 8% to 14%, and it is expected that the proportion of older adults will continue to increase until 2031, when all of the baby boomers will have reached the age of 65 years. Older adults could, therefore, represent between 23% and 25% of the total Canadian population by 2036.

According to a 2010 AARP survey, nearly half of older adults in the United States aged 62–91 years experience occasional or relatively frequent loneliness in their daily lives.[2] In the same AARP study, 45% of individuals aged 65+ years were divorced, widowed, or separated.[2] Isolation was reported among 16.9% of adults over 50 years old, 8.8% of whom reported being chronically lonely. Isolated older adults are at greater risk for poor health and death than those who are well connected, leading to an additional $6.7 billion in federal health spending annually in the U.S.[2] In Canada, it has been noted that loneliness among older adults has great societal costs, as older adults who experience loneliness and isolation are not as engaged in activities such as volunteering, and they are more likely to turn to health care (including emergency department and long-term care) and social services for various supports.[3] Specifically, social isolation and loneliness can increase the risk of developing depression, dementia, and even mortality.[2]

There is substantial evidence demonstrating that loneliness and social isolation among older adults can affect their well-being and cognitive health.[4] There is, however, not a great deal of evidence that technology use amongst older adults helps decrease loneliness and isolation. Recent literature reviews have evaluated different studies examining technology interventions in older adults who face isolation. These reviews showed that technologies such as companion robots,[5] CareTV,[6] and home computers[7] hold potential as promising tools to help decrease isolation, thereby increasing the well-being of individuals.[8,9] Specifically, technology has the potential to increase interpersonal contacts, reduce loneliness, and yield beneficial impacts on a user's overall mental health.[4] Nevertheless, further studies are needed to supply more concrete evaluations of the impact of different types of technological interventions targeted at loneliness and social isolation among older adults.

In particular, there have not been many studies focused on the use of robotic technology interventions in older adults. Recently, there have been various types of robots entering the market that aim to provide social support for older adults, potentially improving their emotional well-being and helping them to live independently.[10] One type of system, known as conversational agents, can provide companionship through social interactions, enabling older adults to connect with family members and friends, as well as offering "talk therapy".[11] These technologies are designed to be user friendly and do not require that users have previous experience with such devices. Another device, called ElliQ, is one example of a new type of robotic technology aimed at reducing loneliness and social isolation in older adults. It differs from other social/companion robots on the market, as it leverages artificial intelligence to create personalized and interactive experiences for the user, while also proactively offering prompts (such as reminding the user to stay hydrated) and suggesting and initiating various activities for the user (such as offering to play a game).

Considering the potential impacts of such technology, this study seeks to investigate how the use of ElliQ, a state-of-the-art, proactive, social robot (using artificial intelligence), at home affects older adults' levels of social isolation and loneliness.

ElliQ

Social companion technology to keep older adults active, engaged, and connected

Intuition Robotics is the creator of ElliQ™, the Active Aging Companion, which aims to help older adults stay active and engaged with a proactive social robot that overcomes the digital divide. ElliQ is an AI-driven, social robot for older adults aimed at reducing social isolation and loneliness by proactively suggesting engaging activities (such as listening to music or watching a TED talk) and making it simple to stay connected with loved ones. ElliQ connects older adults with family and friends by making interactions with technology simple and intuitive. This social companion adapts to the personalities and interests of the older adult, creating a personalized experience and recommending content the user may enjoy such as news, music, TED talks, and cognitive games.

ElliQ is an immobile, tabletop, voice-activated Smart device. Users usually put ElliQ in their living rooms, where they spend most of their days. ElliQ senses what is happening around her through sensors such as cameras and microphones – and she knows how to initiate interactions with her users, such as suggesting that they go for a walk or saying "Goodnight". ElliQ can communicate through expressive body language, speech, sounds, light, and images, and also suggests activities or calls family members.

Intuition Robotics' proprietary cognitive computing technology is what enables ElliQ to be a proactive social robot that initiates interactions with the user. These interactions are personalized and initiated by the system based on contextual understanding and autonomous decision-making algorithms. Using these algorithms, the system also develops an understanding of the user's environment and goals, adapting future suggestions and interactions to the user's behavior patterns and personality traits.

STUDY DESIGN AND METHODS

Research Objectives

The primary goal of this project is to evaluate whether ElliQ has an impact on reducing social isolation and loneliness in older adults who are living alone, while also promoting independence and aging in place. To achieve this, the following research questions will be investigated:

1) How does the use of ElliQ impact the following outcomes in older adults:
   - Loneliness and social isolation;
   - Accessibility to and use of technology;
   - Quality of life, mood, and overall well-being; and
   - Caregiver experience?

2) Do particular characteristics of the older adult population influence these impacts?

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Users

This study is a stratified, parallel, randomized waitlist control study that will be implemented at Baycrest and the Jewish Senior Living Group (JSLG), in which eligible, consented participants will be randomly allocated to the ElliQ (intervention) group or the waitlist control group following a 1:1 allocation ratio. In light of the potential benefits of ElliQ exposure, the waitlist control group will receive the ElliQ intervention after serving as a comparable contemporary control group for the ElliQ intervention group.

Those in the intervention group will first undergo participant characterization and baseline data collection (time 1; week 0). Shortly after, they will be provided with the ElliQ technology in their homes. They will then trial the device for 8 weeks (weeks 1–8). The 8-week trial will be followed with a post-trial data-collection session (time 2; week 9), where they will be asked to return the ElliQ system. At this time, participants will be asked to complete some of the same measures they completed at time 1, and they will also have the opportunity to take part in a one-time, audio-recorded focus group or interview, where field notes will be taken. Following this, the participants will not have a device from weeks 10–17; on week 18, they will be asked to attend a follow-up session (time 3; week 18), where they will be asked to complete some of the same measures they completed at times 1 and 2.

Those who get assigned to the second (waitlist) condition will attend an initial baseline data-collection session (time 1; week 0), where questionnaires related to participant characteristics and baseline measures will be administered. Participants will then wait for 8 weeks to get the ElliQ device (weeks 1–8). After this 8-week wait, participants will be invited to attend another data-collection session (time 2; week 9), where they will be asked to complete some of the same measures that they completed at time 1. Following this session, participants will trial the device for 8 weeks (weeks 10–17). After the 8-week trial, participants will be asked to attend a post-trial data-collection session (time 3; week 18), where they will return the ElliQ system. Participants will then complete a number of the same measures that were completed at times 1 and 2, and attend a one-time, audio-recorded focus group or interview session, where field notes will be taken.

Upon completion of the study tasks (i.e., at the final data-collection session at week 18), each participant's study participation will conclude.

Informal Caregivers

Informal caregivers (e.g., family, friends who provide care for the ElliQ user) may also be enrolled in the study to investigate their experiences with the messaging function of the ElliQ system (user and caregiver pairs will be referred to as "dyads" going forward). Of note, users who do not have caregivers can still enroll in the study.

This will be an exploratory study, insofar as eligible and consented informal caregivers will complete a baseline data collection session for participant characterization; they will also have the opportunity to test the ElliQ messaging function for the 2 months while their study partner (i.e., the ElliQ user) tests the ElliQ system. Informal caregivers will have the opportunity to discuss their ElliQ experience, caregiving experience, and their perception of the impacts the ElliQ system and messaging function had on their study partner's social engagement, loneliness, access to technology, and use of different communication methods (e.g., online, in-person, over the phone, etc.). An audio-recorded focus group or interview (where field notes will be taken) will be held with informal caregivers at the end of the ElliQ users' 2-month test/use period (i.e., on or around week 9 for caregivers of users in the intervention group, or on or around week 18 for caregivers of users in the waitlist control group).

The teams at Baycrest and JSLG will follow a similar protocol (for both users and informal caregivers) and will submit applications for ethics approval through the Baycrest Research Ethics Board and UCSF Institutional Review Board and the JSLG Research Committee.

Key Outcomes

Users

The key outcome measures of interest are the UCLA Loneliness Scale version 3,[16] Duke's Social Support Index,[17] and the Personal Health Questionnaire (PHQ-8).[19] These outcomes will be measured at enrollment, week 9, and week 18.

Informal Caregivers

The primary outcome for informal caregivers will be their qualitative experiences, as discussed during a focus group or interview session. The evaluated impacts will be caregivers' experiences with the use of the ElliQ messaging function, the perceived changes (if any) on communication strategies between caregivers and their study partner (i.e., the ElliQ users), the perceived changes (if any) in the caregiver's ability to provide care for their study partner, and the perceived changes (if any) to the ElliQ user's social engagement, loneliness, well-being, and access to and use of technology.

Sample Size

Users

According to Russell[16] the mean and standard deviation of the UCLA Loneliness version 3 score for a general older adult population is 31.51 and 6.92, respectively. Assumptions for the sample size calculation include a 2×2 factorial design to anticipate potential site differences, a 5.0-point mean difference in the mean change in the UCLA Loneliness Scale version 3 score between the ElliQ intervention and waitlist control groups, and a standard deviation of 15.0 to account for a 2x higher variability compared to Russell's (1996) reported value. For a mean difference of 5.0 and a standard deviation of 15.0, a medium effect size of 0.33 was used to obtain the required sample size.

Using the PASS 16 sample size calculator, a total sample size of 76 (38 per intervention group, 19 per cell in a 2×2 factorial design) achieves 81% power when F tests are used to test the intervention factor (ElliQ versus Waitlist control), site factor (Baycrest versus JSLG), and intervention–site interaction at a 5% significance level and an effect size of 0.33. It is recommended that the ElliQ study recruit a total of 96 participants (48 per intervention group, 24 per cell in a 2×2 factorial design, Table 1) with a contingency of up to a 20% dropout rate (20 expected dropouts).

Table 1. Number of participants to recruit

Factors	ElliQ	Waitlist Control	Site Totals
Baycrest	24	24	48
JSLG	24	24	48
Intervention Totals	48	48	96

Informal Caregivers

Up to 50 informal caregivers will be recruited from Baycrest and JSLG, respectively, as part of this study (up to a total n=100). As this is an exploratory study, there will not be a minimum number of recruited informal caregivers.

Recruitment

Users

For this study, the teams at Baycrest will be recruiting up to 50 participants and JSLG will be recruiting up to 50 participants (i.e., users) at each site, with the aim of recruiting a total of 100 participants. Participants will include residents at Baycrest or JSLG/UCSF, as well as community-dwelling older adults who live within the vicinity of Baycrest or JSLG/UCSF. Recruitment will occur on an ongoing basis at both Baycrest and JSLG.

Recruitment venues
1. San Francisco, JSLG in Partnership with UCSF (n=50)
2. Baycrest (n=50)

Participant consent will adopt the tenets of the Partnership of Consent Protocol,[24] whereby the prospective participant will review the consent form with the research staff. Consent will be obtained from the prospective participant, if they are able to provide it and can answer the teach-back questions; alternatively, if it is clear that the prospective participant is unable to provide informed consent, they will be asked if they would a) like to take part in the study and b) if the research team can contact their substitute decision maker. If the participant assents to both questions, the substitute decision maker (SDM) will be sought and contacted. The research staff member will then go over the consent form for SDMs with the SDM, if applicable. Assent to participate must be obtained by the prospective participant prior to enrolment in the study, and at the start of each study session. Indications of lack of assent or any demonstrations of dissent will be acknowledged as either refusal to consent or refusal to take part in a given study activity, depending on the context in which assent is obtained (i.e., at the consenting session versus at each study session). If consent or assent is not obtained by participant or SDM at any time, their decision to not take part in the study or the activity (or to verify that the participant can take part in the study or the activity) will not impact any current or future care they receive.

Informal Caregivers

Study participants (users) will be asked by the research staff if they have an informal caregiver (e.g., a family member or friend who provides care for them) who might be interested in taking part in the study as well. Those participants who indicate that they do have an informal caregiver who might be interested will be provided with the research staff's contact information to share with their informal caregiver. Interested caregivers who contact the research staff will be provided with more information about the study either over the phone, in person, or over email. Users who do not have informal caregivers can still take part in the study and will not have access to the messaging function.

Study Population: Eligibility Criteria

Inclusion Criteria (Users):
- Older adults aged ≥70 years old and living alone
- Has minimal exposure to technology on a daily basis
- Residents of Baycrest or JSLG/UCSF, or community-dwelling older adults who live near Baycrest or JSLG/UCSF
- Agrees to allow the ElliQ setup team (a member of Baycrest or JSLG/UCSF and Intuition Robotics) to come to their home to install the ElliQ system and to provide training on how to use the system
- Agrees to have the ElliQ setup team test their existing Wi-Fi in their home or agrees to allow for installation of Wi-Fi in their home for the duration of the study (at no cost to the participant)
- Is able to speak clearly and be understood, as exemplified by an app such as Siri/Google speech recognition
- Is able to hear a finger rub with hearing aids in, if applicable
- Is able to read visual content on a screen

Exclusion Criteria (Users):
- Is unable to communicate in oral English
- Is unable to read visual content on a screen
- Has a history or current diagnosis of major psychiatric conditions, excluding depression
- Has sensory impairments (e.g., severe auditory or visual impairments) that would impede an individual's ability to interact with the ElliQ system, which features voice-activated technology and the presentation of content on a screen
- Has an MMSE score <18
- Is currently enrolled in another study

Inclusion Criteria (Informal Caregivers):
- Is an informal caregiver (e.g., a family member, friend, etc.) of an ElliQ study participant
- Lives separately (in a different home) from their study partner (i.e., the ElliQ participant)
- Has access to an Android Smartphone or iPhone running iOS v. 10 or above through which to access Twilio Messenger.
- Is willing and able to use Twilio Messenger to access the ElliQ messaging function
- Understands and abides by the terms and conditions of the messaging app (i.e., Twilio messenger) that links to the ElliQ system
- Is able to speak clearly and in oral English
- Able to hear audio and see and read content on a screen

Exclusion Criteria (Informal Caregivers):
- Individuals who are not an informal caregiver to an ElliQ study participant
- Lives in the same home as the ElliQ study participant
- Does not have access to an Android Smartphone or iPhone running iOS v. 10 or above through which to access Twilio Messenger
- Is unable or unwilling to use Twilio Messenger to access the ElliQ messaging function
- Refuses to abide by the terms and conditions of Twilio Messenger
- Is unable to speak or read in English
- Is unable to hear audio or see/read content on a screen

Randomization

Users

Once participants have been screened, deemed eligible for the study, completed the informed consent process, and have completed the preliminary baseline measures, they will be randomly assigned to either the active condition or a waitlist control group. Stratified randomization with allocation concealment will be implemented in the study. Separate randomization schedules containing unique three-digit numbers with corresponding 1:1 intervention allocation will be generated by a biostatistician at Baycrest using SAS 9.4. Each site (Baycrest and JSLG) will receive randomization schedules for up to 50 participants. The point persons at Baycrest and JSLG will obtain the randomization schedule for their respective sites. The point person(s) at each site will prepare 50 opaque sealed envelopes each containing a unique three-digit number from their site-specific randomization schedule and will give these envelopes to the recruiting research assistants. Once an eligible individual consents to participate in the study, the recruiting research assistant will pick a sealed envelope and use the three-digit number as the consenting participant's study ID. The recruiting research assistant must coordinate promptly with the point person in charge of keeping the randomization schedule to determine the intervention allocation assigned to the specific three-digit number obtained. The research assistant will then inform the consenting and eligible participant regarding their intervention group assignment and proceed with the next steps of study implementation.

ElliQ Implementation

Users

Those who enroll in the study will receive a ~1.5-hour visit from a member of the ElliQ setup team at a mutually agreed upon appointment time, which may include Baycrest and/or study sponsor staff (the ElliQ setup team; they will have Tri-Council Policy Statement 2 [TCPS2] certification). The ElliQ setup team will install the ElliQ system and verify the functioning of the participant's Wi-Fi network. This process may include the following:

- Setup time (1 hour):
  - Testing of current Wi-Fi capabilities or, if not available, installation of Wi-Fi
  - Provision of additional bandwidth, if the participant's current Wi-Fi capabilities are too low to accommodate the ElliQ system
  - Installation of the ElliQ system, which includes determining an optimal location for the ElliQ system (e.g., where there is Wi-Fi connection, a nearby wall port, and the absence of tripping hazards)
- Training the participant on how to use the ElliQ system, which will include:
  - An overview of ElliQ's features and functions
  - A walkthrough of the user manual
  - Answering any questions the participants may have

Once the setup and training are complete, the system will then remain in the participant's home for a total of 8 weeks. Baycrest or JSLG/UCSF research staff's telephone number will be provided for support in case participants experience technical issues during this time.

For those in the waitlist control, they will undergo this same process after their 8-week wait. Study staff will check in with participants at the midway point (i.e., at week 4 of the ElliQ testing period) to ask about any problems/concerns. Following the 2-month ElliQ test/use period, the ElliQ setup team (who will have TCPS2 certification) will come to the participant's home to remove ElliQ and the Wi-Fi setup, if applicable.

Informal Caregivers

Those informal caregivers who enroll in the study will attend a baseline session of up to 1 hour immediately after the informed consent process. At this session, informal caregivers will be trained on how to access and use Twilio Messenger as part of the ElliQ messaging function. They will be instructed to use the function for as long as they feel comfortable and willing to do so for the duration of their study partner's 2-month ElliQ test/use period. Informal caregivers will be provided with study staff's contact information, should they have any questions about the device or the study. They will also be informed that they can take as much time as they need to review Twilio's terms of service and privacy statement before agreeing to use the messaging function (where messaging data will be captured and stored by Twilio and not collected, accessed, or used for study purposes).

Data Collection

Users

The following data will be collected as part of the study.

Time 1 (Baseline and Participant Characterization)

Medical/Study Data

- Participant characterization
    a) Demographics questionnaire
    b) SF-12[12]
    c) Lawton's IADL Scale[13]
    d) Mini-Mental State Examination (MMSE)[14]
    e) Caregiver status questions
- Access to technology/technology literacy
    a) Computer Proficiency Questionnaire[15]
- Loneliness and social isolation
    a) UCLA Loneliness V3 Scale[16]
    b) Duke's Social Support Scale[17]
- Quality of life
    a) OPQOL[18]
- Mood
    a) Personal Health Questionnaire (PHQ)-8[19]
    b) Visual Analog Mood Scale (VAMS)[20]
    c) Brief Mood Introspection Scale (BMIS)[21]

During the Study Period

Product Usage Data (Captured by ElliQ)

The ElliQ system is capable of capturing data on its own, as per its commercially available functions. There are two primary types of data that the ElliQ system can capture; for example:

Product Usage Data – Metrics
- Number of proactive plans initiated by the ElliQ system (e.g., when the ElliQ system initiates small talk or suggests an activity)
- Number of reactive plans (i.e., ElliQ responding to the user)

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- Plan context (proactive or reactive)
- Plan type (video, small talk, other)
- Total number of plans per time unit
- Time and date of plan
- The time the device is turned on or off

Product Usage Data – Personal Interactions
- Facial recognition
- IP address
- Speech intent (mapped to ElliQ's library of intent types)
- TextHeard (speech-to-text data)
- Content shared with the ElliQ system (e.g., videos, photos, and other content shared by the user with the ElliQ system)
- Possible capture of background interactions via speech-to-text data

These data are based on a user's interactions with the device. Facial recognition data will be collected, as it is an integral component of the proprietary technology used to operate the device. Specifically, since ElliQ is a proactive social robot, it uses the facial recognition data to determine that the user is within range of the device, and this prompts the device to greet or suggest activities to the user. This device has the ability to "look up" to a user and "see" the user's face to interact with the user on a more personal level.

Caregiver/User Dyads Only

In addition to the Medical/Study Data and ElliQ Product Usage Data detailed above, the caregiver/user dyads enrolled in this study will also have the following data collected as part of their study involvement, by virtue of using the messaging app.

Twilio Product Usage Data: Metrics

The user/caregiver dyads enrolled in this study will have the following Twilio data collected and used by Twilio Messenger (according to Twilio's commercially available terms of service and privacy statement).

- Dates when messages were sent/received between ElliQ and the Twilio Messenger app
- Times when messages were sent/received between ElliQ and the Twilio Messenger app
- Number of messages sent/received between ElliQ and the Twilio Messenger app

Intuition Robotics will have access to these same data via ElliQ.

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Twilio Product Usage Data: Personal Interactions

The user/caregiver dyads enrolled in this study will have their messenger function data collected and used by Twilio (in accordance with Twilio's commercially available terms of service and privacy statement). The following are examples of data collected by Twilio:

- Text, video, or voice messages shared between caregivers and ElliQ users
- Photos and other files shared between caregivers and ElliQ users

Data-Collection Sessions (Times 2 and 3)

- Access to technology/technology literacy
    - a) Computer Proficiency Questionnaire[15]
- Loneliness and social isolation
    - a) UCLA Loneliness V3 Scale[16]
    - b) Duke's Social Support Scale[17]
- Quality of life
    - a) OPQOL[18]
- Caregiver status
    - a) Caregiver status questions
- Mood
    - a) Personal Health Questionnaire (PHQ)-8[19]
    - b) Visual Analog Mood Scale (VAMS)[20]
    - c) Brief Mood Introspection Scale (BMIS)[21]
- ElliQ Companionship
    - a) ElliQ Companionship Questionnaire

Time 2 (Intervention group) or Time 3 (Waitlist control)

- Interview/focus group question guide

Informal Caregivers

The following data will be collected from the informal caregivers as part of this evaluation:

Time 1 (Data Collection Session 1)

Medical/Study Data

Participant Characterization
- Demographics questionnaire

Twilio Product Usage Data: Account Setup

Caregivers enrolled in this study will also have information obtained by Baycrest, JSLG/UCSF, and Intuition Robotics to setup the messaging app. The information collected for these purposes will include:

- First name, last name, gender, and profile photo (to allow the user from the dyad to be able to identify the caregiver when the caregiver calls/messages the user)
- Cell phone number (to setup the Twilio Messenger app)
- Email address (to verify the Twilio Messenger account)

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In order to set up the messaging function, caregivers will need to provide Intuition Robotics with their first name, last name, gender, profile photo (preferably one of themselves to indicate to the user who is messaging them), email address, and telephone number. These data are being collected to tailor the users' and caregivers' experiences with the messaging function, as per the commercially available functions of the device.

All data captured by Twilio may be collected and used by Twilio as per Twilio's terms of service and privacy statement.

Time 2 (Follow-Up Session)

Follow-Up Session (end of the 2-month test/use period)
- Interview/focus group question guide

Other Data (All Participants)

- Technical support logs to document potential issues that arise as participants use the device

Data Analysis
Quantitative analysis

Participant characterization (Users and Informal Caregivers)

Baseline characteristics of the participants in the two intervention groups will be summarized by site through descriptive statistics, frequencies, or proportions. Comparisons between intervention groups and between sites will be performed to determine whether a balance between intervention groups has been achieved as a result of the randomization process conducted at the site level. Analyses will include independent *t*-tests for continuous data or chi-squared tests for proportions. If the distribution of any continuous measure is markedly skewed or contingency tables for proportions contain cell sizes <5, non-parametric tests, namely the Mann–Whitney U/Wilcoxon rank-sum test and Fisher's exact test, will be conducted in place of the independent *t*-test and chi-squared test, respectively.

Primary Analysis (Users)

Analysis of the effect of the intervention on the key outcome measures will be performed using an intent-to-treat approach, thus including all randomized participants. The primary analysis will include participants in the ElliQ intervention group and the comparable contemporary waitlist control. If there is balance in participants' characteristics across the two sites, evaluation of changes in the outcomes will only include the intervention as the independent variable of interest. In this case, the mean change in the outcome scores from Baseline to Post 1 (Session 2) will be calculated for each intervention group. The calculated mean change will be compared between intervention groups using an independent *t*-test. Effect sizes within an intervention group (standardized response means) and between groups will be calculated to measure the magnitude of mean differences. In the case of an imbalance between sites, the primary analysis will be a linear regression model involving the change in primary outcome as a function of intervention, site, and intervention–site interaction. Measurements of the primary outcome obtained at Time 3 for the ElliQ intervention group and on the waitlist control after being given ElliQ will not be included in this primary analysis.

Sub-Analyses (Users and Informal Caregivers)

Sub-analyses will involve the assessment of the outcomes when participants are exposed to ElliQ and evaluating differences in the trends in bi-weekly engagement survey responses between intervention groups.

To evaluate the change in the outcomes before and after exposure to ElliQ, outcome measurements obtained from the ElliQ intervention group at Baseline and Time 2 will be pooled with the measurements obtained from the waitlist control group before (Time 2) and after (Time 3) exposure to ElliQ. Change analysis will be conducted through the paired t-test and standardized response mean.

To assess sustained impact of ElliQ on the outcomes, the trajectory of the primary outcome from baseline, post, and follow-up within the ElliQ intervention group will be evaluated through a linear mixed-effects model with a random intercept to account for the intra-individual variability in repeated measurements per participant. The model will involve the primary outcome and time as the independent variable, which will be treated as a factor with three levels representing the three time points.

To determine the difference in the trend of bi-weekly engagement survey responses between intervention groups, a linear mixed-effects model with a random intercept for the scaled response as a function of time, intervention, and time-intervention interaction will be performed.

Level of significance for the statistical tests will be set at 0.05 and analyses will be carried out using SAS 9.4.

Qualitative analysis

Where possible, focus groups with up to 6–8 participants at a time will be scheduled with study participants (users and informal caregivers) at week 9 (intervention group) or week 18 (waitlist control group). Where a focus group session is not feasible (either due to participant's schedules or preferences), individual interviews will be held instead. Those informal caregivers who are unable to attend an in-person session may be invited to an audio-recorded telephone interview. The focus groups/interviews will be facilitated by research staff, and a semi-structured interview guide will be used. The questions may be modified based on the nature of the discussion that emerges during the session, but any additional questions will remain topical and will explore participants' experiences with ElliQ across numerous domains.

The focus group/interview sessions will be audio-recorded and field notes will be taken (either by the interviewer or by another study staff member). In the event that a participant is not comfortable with attending an audio-recorded session, they will be informed that de-identified field notes will be taken instead. Those who do not wish to be audio recorded will not be withdrawn from the study.

The audio-recorded focus group/interview sessions will be transcribed by a member of the study team at each respective site (i.e., Baycrest or JSLG/UCSF). All transcripts, field notes, and responses to open-ended survey questions will be reviewed for accuracy and to ensure that all information is de-identified by the respective site. The de-identified transcripts, field notes, and open-ended survey questions will then be coded and analyzed by a member of the research study team.

Following these preliminary steps, the transcripts, field notes, and responses to open-ended survey questions will be uploaded into qualitative analysis software (NVivo for transcripts and field notes, Excel for open-ended survey questions). Baycrest study staff will initially perform case, category, and attribute coding to distinguish between study groups (intervention versus waitlist control). This will be followed by in vivo coding and content coding of the interviews, as well as in vivo coding and line-by-line coding for the field notes. Following this initial coding, themes and sub-themes will be generated using thematic analysis, adopting the tenets of phenomenology where feasible, particularly when exploring participants' reported feelings and lived experiences.

For questions that focus on the technical aspects of the ElliQ system (such as those related to the ElliQ's technical functions or user experience that are solely focused the device's performance), focused coding will be used to generate themes, which will be based on the semi-structured interview guide questions.

Finally, matrix coding and analysis will be used to assess whether there are differences in the experiences between those in the intervention versus waitlist control groups. Thematic graphics and tables may be generated if there are observable differences in the themes between conditions.

De-identified quotes may be used to illustrate the various themes generated in the analysis. A report featuring all the themes, subthemes, associated de-identified quotes, and tables/images will be compiled and disseminated to the research team and other key stakeholders involved in this project.

Participant Withdrawal

Participants (ElliQ users and informal caregivers) will be withdrawn from the study if they are no longer willing or able to complete study procedures. Participants will be informed that their participation is entirely voluntary, and they can withdraw their participation at any time; they will be notified that their decision to withdraw from the study will not impact the care that they or their loved ones receive at any of the study sites. Participants will also be asked if they would like their data included or removed from the study upon their withdrawal, with the exception that focus group data will need to be retained given that the discussion is contingent upon group interactions. Data will be included in the study if a participant does not express a preference (e.g., in the case of those lost to follow up). Participants will be asked to describe their reasons for withdrawal, if they feel comfortable disclosing this information.

Final Summary

The present longitudinal study investigates the hypothesis that a social, proactive robot such as ElliQ could decrease feelings of loneliness or isolation among older adults. More specifically, a pre- and post-design and waitlist control–active intervention group comparison with focus group/interview analyses will be employed to assess whether using ElliQ leads to any improvement in social isolation/loneliness among ElliQ users. Moreover, this study will also explore the impacts of ElliQ' messaging function, among those who choose to use it, on caregiver experience, caregiver and user social engagement and quality of life, and communication strategies, particularly mediated by technology use. Currently, there is insufficient literature that has investigated the impact of social robotic technology in the field of geriatrics and social isolation. The present study could provide support for this model and its expansion to the wider geriatric population in Canada and globally.

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